

REMARKS

I. Introduction

Applicants thank the Examiner for the withdrawal of all previous rejections.

No amendments to the claims are made at this time.

II. Nonstatutory Obviousness-Type Double Patenting Rejection

Claims 9-33 are rejected by the Examiner on the grounds of nonstatutory obviousness-type double patenting over claims 1-23 of U.S. Patent No. 6,793,664 (“the ‘664 patent”) and claims 1-15 of U.S. Pat. No. 7,122,018 (“the ‘018 patent”). (Office action at 2.) The Examiner states that “[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because both patents like the instant application disclose a method of promoting the healing of a wound comprising exposing the wound to a nitric oxide bath. The patents do not teach the application of a wound-healing agent to the wound in addition to the nitric oxide. However, the patented claims employ ‘comprising’ language, which allows for the inclusion of a wound-healing agent.” (*Id.*) Applicants respectfully traverse this rejection because the Office action has not even established a *prima facie* case of nonstatutory obviousness-type double patenting.

A nonstatutory obviousness-type double patenting rejection is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinguishing from claims in a first patent. MPEP § 804 (emphasis added). Thus, in order for the Examiner’s rejection to be proper, the claims of the ‘644 and ‘018 patents must render obvious the claims of the present invention.

The limitation of applying a wound healing agent to damaged tissue and variations of this limitation is recited in all the independent claims (i.e. claims 9, 10, 11, 12, 13, 14, and 15) of the present application. In contrast, the CLAIMS of the ‘664 and ‘018 patents are silent as to a wound healing agent. Thus, the CLAIMS of the ‘664 and ‘018 patents do not suggest the claims of the present application.

The Office action’s assertion that the claims of the present application are obvious because the claims of the ‘644 and ‘018 patents “employ ‘comprising’ language, which allows for the inclusion of a wound-healing agent” (Office action at 2) is patently baseless. The “comprising of” transitional language in the claims of the ‘644 and ‘018 patents inarguably is an insufficient basis for a person of ordinary skill in the art to conclude that the present application’s claims are obvious variations of the claims of the ‘644 and ‘018 patents. The Office action’s rejection lies on the clearly false assumption that the “comprising of” language suggests all other additional subject matter that hypothetically could be added to the subject matter recited in the claim. To the contrary, nothing about “comprising of” suggests any other subject matter, whether it be the administration of wound healing agents or anything else.

Furthermore, even a cursory examination of the present claims reveals that there are many additional limitations recited in the present claims besides the application of wound healing agents that are not taught by the CLAIMS of the ‘644 and ‘018 patents. To establish obviousness under 35 U.S.C. § 103, “the prior art reference (or references when combined) must teach or suggest all the claim limitations.” (MPEP § 706.02(k). “Any obviousness-type double patenting rejection should make clear: ... (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the

claim at issue would have been an obvious variation of the invention defined in a claim in the patent.” (MPEP § 804(B)(1).) Because the Office action does not even discuss how the ‘644 and ‘018 patents allegedly render obvious these other claim limitations, the Office action has not established a *prima facie* case to support this rejection.

Discussed below are some of the additional limitations, besides the application of wound healing agents, that distinguish the claims of the present application from the claims of the ‘644 and ‘018 patents.

The ‘664 patent claims methods of treating infected tissue with topical nitric oxide exposure. (‘664 patent at independent claims 1, 10, 11, 13, and 19.) The ‘018 patent claims methods to promote healing of a wound and methods of reducing scarring in the healing process of a wound. (‘018 patent at independent claims 1 and 12.)

Independent claims 9, 10, 11, 12, 13, and 15 of the present application all recite the limitation that the damaged tissue is “surrounded by an air impermeable wound cover.” The CLAIMS of the ‘644 and ‘018 patents do not recite an “air impermeable wound cover.” Although the claims of the ‘644 patent teach a “bathing unit,” this bathing unit is not the “air impermeable wound cover” of the claims of the present application. For example, Figure 3 of the present application depicts a bathing unit 15 used in conjunction with a wound cover 17. (page 11, line 21 – page 12, line 2.) Thus, a bathing unit and a would cover are distinguishable apparatuses.

Independent claims 9, 10, 11, and 12 of the present application all recite the limitation of “allowing at least a portion of the gaseous nitric oxide to contact the air adjacent to the air impermeable wound cover through the air impermeable wound cover.”

The CLAIMS of the ‘644 and ‘018 patents do not teach allowing nitric oxide gas to contact air outside of an air impermeable wound cover through the cover.

Independent claim 10 of the present application recites the limitation of “wetting, dampening, or moistening the damaged tissue following the gaseous nitric oxide exposing step.” The CLAIMS of the ‘644 and ‘018 patents do not teach wetting, dampening, or moistening the damaged tissue.

Independent claim 13 of the present application recites the limitation of “administering exogenous nitric oxide to tissue flap and surrounding damaged area in order to promote flap viability and increase local blood flow to donated tissue.” The CLAIMS of the ‘644 and ‘018 patents do not teach exposing a tissue flap to nitric oxide in order to promote flap viability and increase local blood flow to donated tissue.

In view of the many limitations recited in the independent claims of the present application (i.e. claims 9, 10, 11, 12, 13, 14, and 15) that are not taught or suggested by the ‘644 and ‘018 patents, it is evident that the present independent claims are not obvious in light of the CLAIMS of the ‘644 and ‘018 patents. Accordingly, the dependent claims of the present application also are not obvious in light of the claims of the ‘644 and ‘018 patents. Applicants respectfully request withdrawal of the nonstatutory obviousness-type double patenting rejection.

III. Provisional double patenting rejection

“Claims 9-33 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 46-89 of copending Application No. 20050137521 (10/944479) and claims 1-39 of copending Application No. 20050217679 (11/107618).”

... The [applications] do not teach the application of a wound-healing agent to the

wound in addition to the nitric oxide. However, the patented [sic] claims employ ‘comprising’ language, which allows for the inclusion of a wound-healing agent.” (Office action at 3.) Applicants respectfully traverse this rejection.

C. The ‘479 application

The ‘479 application was filed on September 17, 2004. The present application was filed on July 8, 2003. Accordingly, if no other grounds for rejecting the present application are found, the provisional double patenting rejection should be withdrawn and the present application allowed to issue without a terminal disclaimer because the present application is the earlier filed of the two applications. MPEP 804(B)(1). Thus, Applicants respectfully request the removal of this rejection.

D. The ‘618 application

The ‘618 application was filed on April 14, 2005. The present application was filed on July 8, 2003. Accordingly, if no other grounds for rejecting the present application are found, the provisional double patenting rejection should be withdrawn and the present application allowed to issue without a terminal disclaimer because the present application is the earlier filed of the two application. MPEP 804(B)(1). Thus, Applicants respectfully request the removal of this rejection.

III. Conclusion

Applicants respectfully request that the nonstatutory obviousness-type double patenting rejections of claims 9-15 and 17-33 be withdrawn and a Notice of Allowance be issued for all pending claims.

If the undersigned can be of any assistance to the Patent Office, a telephone call is respectfully requested. If any fees are required by this filing, the Commissioner is authorized to charge Sidley Austin LLP's Deposit Account # 50-1597.

Respectfully Submitted

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Date: August 21, 2007

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